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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,161	09/10/2001	Tsunetoshi Honma	067242-0152	9225

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EXAMINER
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COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/02/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/936,161

Applicant(s)  
HONMA et al.

Examiner  
Brenda Coleman

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1624

## DETAILED ACTION

Claims 8-19 are pending in the application.

### *Priority*

1. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/JP00/01223, filed March 2, 2000.” is suggested.

### *Specification*

2. The disclosure is objected to because of the following informalities:

#### **608.01(m) Form of Claims**

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with “**I (or we) claim,**” “**The invention claimed is**” (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Technology Center (TC) technical support staff. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a

Art Unit: 1624

plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is the Wands factors which are used to evaluate the enablement question. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace [2.2.1] or [3.1.1] bicyclic compounds. The scope of “prodrug” is not adequately enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

Art Unit: 1624

The instant compounds of formula (I) wherein the prodrugs are not described in the disclosure in such a way the one of ordinary skill in the art would not know how to prepare the various compounds suggested by claims 1-7 and 10. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 15-17 are substantial duplicates of claim 14, as the only difference is a statement of intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.
- b) Claim 18 provides for the use of the compounds according to claim 8, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Art Unit: 1624

- c) Claim 19 indicates "comprises administering the compound according to claim 8" which is unclear as to whether a therapeutically effective amount of the compound is administered or if this is indicative of a subject in need thereof.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

Art Unit: 1624

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 8-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohtani et al., U.S. 6,384,075 and 6,172,113. Ohtani teaches the compounds, compositions and method of use of the compounds where X<sup>1</sup> is phenyl, isoxazole, thienyl, benzothienyl, etc.; X<sup>2</sup> is bond, O, SO, SO<sub>2</sub>, NH, -N=N-, -C(=O)-NH-, -NH-C(=O)-, -CH<sub>2</sub>-CH<sub>2</sub>-, -CH=CH-, C(=O), CH<sub>2</sub>, etc.; and X<sup>3</sup> is phenyl, imidazole, tetrazole, pyridyl, thienyl, thiadiazole, etc. See table 2a.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtani et al., U.S. 6,384,075 and 6,172,113. The generic structure of Ohtani encompasses the instantly claimed compounds (see Formula I, column 2) and for the same uses as claimed herein. Examples in Table 2a differ only in the nature of the Y', m, Z, A, B, R, X<sub>1</sub>, X<sub>2</sub> and X<sub>3</sub> substituents. Column 2, lines 20-62 defines the substituent Y' as a bicyclic ring, i.e. [2.2.1]cycloheptane, dimethyl substituted [3.1.1]cycloheptane, etc., A is alkylene which is intervened by hetero atom or phenylene, contains oxo group, and/or has an unsaturated bond; B is hydrogen, alkyl, aralkyl or

Art Unit: 1624

acyl; R is COOR<sub>1</sub>, CH<sub>2</sub>OR<sub>2</sub> or CON(R<sub>3</sub>)R<sub>4</sub>; X<sub>1</sub> is a single bond, phenylene, naphthylene, thiophenediyl, indolediyl, or oxazolediyl; X<sub>2</sub> is a single bond, -N=N-, -N=CH-, -CH=N-, etc., and X<sub>3</sub> is alkyl, alkenyl, alkynyl, aryl, aralkyl, heterocyclic group, cycloalkyl, etc. Compounds of the instant invention are generically embraced by Ohtani in view of the interchange ability of Y', A, R, X<sub>1</sub>, X<sub>2</sub> and X<sub>3</sub> substituents of the bicyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example Y' is ring [2.2.1]cycloheptane, m is 0, X<sub>2</sub> is -N=N-, R<sub>2</sub> is H or Me as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground



Art Unit: 1624

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 8-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,384,075. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant invention are embraced by the compounds of Ohtani where  $X_1$  is phenylene, naphthylene, thiophenediyl, indolediyl or oxazolediyl; and  $X_3$  is aryl or a heterocyclic group.

9. Claims 8-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,172,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant invention are embraced by the compounds of Ohtani where  $X_1$  is phenylene, naphthylene, thiophenediyl, indolediyl or oxazolediyl; and  $X_3$  is aryl or a heterocyclic group.

10. Claims 8-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/297,065. Although the conflicting claims are not identical, they are not patentably distinct

Art Unit: 1624

from each other because the compounds of the instant invention are embraced by the compounds claimed in copending Application No, 10/297,065.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman

Primary Examiner AU 1624

June 30, 2003